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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,446	01/18/2000	HUGH W. PRICE	7841-89	5954

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KNOBLE, YOSHIDA & DUNLEAVY
EIGHT PENN CENTER
SUITE 1350, 1628 JOHN F KENNEDY BLVD
PHILADELPHIA, PA 19103

EXAMINER	
HINES, JANA A	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/402,446	Applicant(s) PRICE ET AL.	
	Examiner Ja-Na Hines	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *23,25,26,31-39,57,59,60 and 64-73*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *74-80*.
   Claim(s) withdrawn from consideration: *None*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER

S. 0-0

The rejection of claims 74 and 78-80 under 35 U.S.C. 102(b) as being anticipated by Friesen (CA 1,201,063) is maintained for reasons already of record. The rejection was on the grounds that Friesen teaches an aqueous immune globulin preparation for parenteral administration comprising a highly pure polyclonal anti- RhoD immune globulin and at least one non-ionic surface active agent.

Applicants' assert that the examiner has misinterpreted the definition of non-ionic surface active agents provided by the specification. However, contrary to applicants' assertions the examiner has not misinterpreted the definition. Page 18, beginning at line 19, the specification states that such agents can be any agent that can prolong the serum half-life of an immune globulin. Mannitol meets the definition set forth by applicants specification. The specification then recites that preferably, the surface agents are of the Tween or Span type. This distinction teaches alternative definitions of the agents. Applicants have asserted that mannitol does not the definition of the Span type agents. However the definition provided in the specification is not limited to the properties of Span type agents. Thus applicants' argument is not persuasive since applicants own specification teaches that mannitol is encompassed by other types of surface agent, i.e., the Tween type agents. Applicants' specification provided a broad definition and in view of applicants broad definition and the fact that mannitol is encompassed by the definition provided in the specification for non-ionic surface active agents, the rejection is maintained since applicants' arguments are not persuasive.

The rejection of claims 74-76 and 80 under 35 U.S.C. 102(b) as being anticipated by DeBurgh Bradley et al., (CA 1,303,533) is maintained for reasons already of record. The rejection was on the grounds that Bradley et al., teach an aqueous immune globulin preparation for parenteral administration comprising a monoclonal or polyclonal anti- RhoD immune globulin and at least one non-ionic surface active agent which are both sorbitan esters of a fatty acid, and polyoxyethylene sorbitan esters of a fatty acid, just as instantly claimed.

Applicants' assert that Bradley does not provide any suggestion that Tween or any other surfactant can be advantageous in immune globulin preparations. In response to applicants' argument that the instantly claimed composition can be advantageous in immune globulin preparations, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967). In the instant case the composition of Bradley meets the instantly claimed limitations since there are no structural differences. The statements about the properties associated with the components of the composition are irrelevant. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Moreover, products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658(Fed. Cir. 1990).
Therefore applicants' arguments are not persuasive and the rejection is maintained.

Applicants' believe that the prior art is distinguishable because the prior art provides compositions for use in assays and not for parenteral administration use. However the MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Therefore applicant's argument is not persuasive especially when considering that the patent discloses compositions comprising the same instantly claimed components, thus it meets the limitations of the claims. The fact that the patent discloses that the composition may be used with other assays does not distinguish the instant claims over this art. Therefore applicants assertions drawn to the additional uses are irrelevant. The disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims, since the prior art teaches compositions with exactly the same components.

Applicants' also state that Bradley refers to ingredients not approved for parenteral formulation or use with bovines. However the instant claims recite "comprising" and this transitional term is synonymous with "including," "containing," or "characterized by," and is inclusive or open-ended and does not exclude additional, unrecited elements. Moreover, the composition of Bradley meets the instantly claimed structural limitations of the composition, therefore arguments drawn to other uses, and the potential for the composition to contain additional ingredients is irrelevant. Thus applicants' arguments' about specific properties or abilities of the composition is not persuasive and the rejection is maintained.